

§102 Rejections

1. The Examiner rejected claim 1-8, 12 and 14-16 as being anticipated by Ullman et al. (US 6,406,913). In the Examiner's communication to the Response After Final the Examiner states that Applicants arguments and reliance on lines 33-34 of Ullman et al. does not appear to address the passages in Ullman et al. cited by the Examiner and the relevance was not clear. In addition, the Examiner asked Applicant to expound on the analogous situation described by Applicant.

In the prior Office Action, the Examiner stated that the term "capable of selectively binding dissociated first binding species without detrimentally affecting the signal strength" does not structurally differentiate the invention from Ullman et al. Applicants arguments discussed above were meant to demonstrate that the term does structurally differentiate the claims from Ullman et. al.

Applicants ask the Examiner to review the phrase as a whole. The second substrate has binding partners capable of selectively binding dissociated first binding species without detrimentally affecting the signal strength.

The binding partners disclosed in Ullman et al. do not disclose or suggest that the Ullman et al binding partners selectively bind dissociated first binding species. In fact and to the contrary, Ullman et. al. at lines 33 to 34 state that the binding partners are attached to the particles. There is no selective binding of the binding partners in Ullman et al. to dissociated first binding species. Since the binding partners of Ullman et al do not selectively bind dissociated binding species the language in the claims is distinguishable from Ullman et al. The language in the claims describes the second substrate and serves to distinguish the claims structurally from Ullman et al in much the same way as an antibody specific to hCG does not anticipate an antibody specific to cyclosporine. That is, Ullman et al does not teach the binding partners disclosed in the present invention. Thus, Applicants respectfully request that the rejection be withdrawn.

2. The Examiner also repeated the rejection relating to Ullman's describing cavities on the binding species stating that claim 7 does not contain require the material (substrate) to be permeable. The Examiner is correct in that statement – the substrate is not required to be permeable. Regardless, the Examiner stated that Ullman teaches cavities on the solid support (the "substrate") referring to Ullman et al. at col. 19 at about line 39. Applicants point is that

Ullman is describing cavities on the binding material (e.g. the antibody or the like) NOT the solid support or substrate material. Col. 19, lines 36 to 43 states:

Specific binding – the specific recognition of one of two different molecules for the other compared to substantially less recognition of other molecules. Generally, the molecules have areas on their surfaces or in cavities giving rise to specific recognition between the two molecules. Exemplary of specific binding are antibody-antigen interactions, enzyme-substrate interactions, polynucleotide interactions, and so forth.

Thus, Applicants respectfully request that the rejection be withdrawn.

3. In the prior action, the Examiner rejected claim 12 stating that Ullman et al. teach a reagent used in a sandwich assay comprising a first binding species (col. 37, lines 58+) wherein a first portion (col. 38, lines 7-9) is attached to the first substrate and a second portion is dissociated from the first substrate and the second portion binds to a second substrate. Applicants traverse. Applicants stated they have not found in Ullman et al. where it is disclosed that a second portion of the first binding species is dissociated from the first substrate and then binds to a second substrate. In this Final Office Action, the Examiner states that Ullman et al. describe a second portion of the first binding species (the beta subunit of TSH) that is dissociated from that substrate. Applicants point out that this is not a first portion of a first binding species and second portion of the first binding species. Instead, in this embodiment of Ullman et al. a first binding species (antibody for TSH) is covalently linked to a chemiluminescent molecule. See, Ullman et al. at col. 37, lines 58-60. At col. 37, line 64 to col. 38, line 5, it can be seen that a second binding species (a different antibody to TSH) is linked to a latex particle (col. 38, lines 3-5). The latex particle is also linked to rose Bengal (col. 37, line 64 to col. 38, line 3). Ullman et al. further distinguishes the two antibodies. One of the two antibodies recognizes the alpha subunit of TSH, the other antibody recognizes the beta subunit of TSH. The hormone TSH is comprised of the alpha unit of TSH linked to the beta unit of TSH forming one molecule. Thus, when TSH is present in a sample, the TSH is sandwiched by the two different antibodies. There is simply no first portion of a binding species attached to a substrate and a second portion of the binding species dissociated from the substrate.

Thus, Applicants submit that the claims as amended are not anticipated by Ullman et al. and respectfully request that the rejections be withdrawn.

Applicants submit that the amended claims are patentably distinct from Ullman et al. If the Examiner disagrees or would like to discuss the rejections, Applicants respectfully request an interview at a time convenient for the Examiner. The Examiner is encouraged to contact the undersigned if the Examiner has any matter that the Examiner would like to address.

Respectfully submitted,



Cynthia G. Tymeson
Attorney for Applicants
Reg. No. 34,745

Dade Behring Inc.
Legal Dept. – Patents
1717 Deerfield Rd.
Deerfield, IL 60015
Phone: 302-631-0360